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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,345	03/25/2002	Jan Gerrit Garssen	5034US	8607

7590 05/10/2005

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,345	GARSSEN	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23December2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

1. Applicants' Response to Office Action, received 23December2004, is acknowledged. Claims 1, 2, 10, 14, 18, and 19 have been amended.

2. Claims 1-7, 10-16, 18, and 19 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claim.

4. The rejection of claims 1-7, 11, 12, 15, 16, 18, and 19 under 35 U.S. C. 112, second paragraph, indefiniteness for "derived" is withdrawn in light of the amendment of claim 1.

5. The rejection of claims 1-5 and 11-14 under 35 U.S.C. 102(b) as being anticipated by Bell et al (*Neuropathology and Applied Neurobiology*, 23(1):26-35, 1997) is withdrawn in light of the amendment of the claims and applicants' arguments.

6. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Bell et al (*neuropathology and Applied Neurobiology*, 23(1):26-35, 1997) in view of Schreuder et al (WO97/37227) is withdrawn in light of the amendment of the claims and applicants' arguments concerning Bell et al.

7. The rejection of claims 15 and 16 under 35 U.S.C. 103(a) as being unpatentable over Bell et al (*neuropathology and Applied Neurobiology*, 23(1):26-35, 1997) in view of Prusiner et al (U.S. Pat. No. 5,565,186) is withdrawn in light of the amendment of the claims and applicants' arguments concerning Bell et al.

Rejections Maintained

8. The rejection of claims 10, 13, and 14 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained for reasons of record.

The amendment of claim 10 deletes only one instance of "derived", line 5. Line 2 of the amended claim 10 retains the indefinite "derived". Claim 13 retains the indefinite "derived". Claim 14 depends from claim 13, but does not correct the indefiniteness.

9. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained for reasons of record.

The rejection of claim 19 is maintained because although the claim is amended, deleting "designed", the inserted "adapted" is indefinite because there is no recitation for how one "adapts" the kit parts.

10. The rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Bell et al (*Neuropathology and Appliced Neurobiology*, 23(1):26-35, 1997) is maintained for reasons of record.

Newly amended claims 18 and 19 are still drawn to a kit of parts "comprising" a carrier matrix, a buffer, a solution of guanidine thiocyanate or a functional equivalent thereof, and an antibody that recognizes PrP^{Sc}. Due to the open language that the kit of parts "comprises" the listed components, the kit may also contain any other components. Thus, as stated in the original rejection, Bell et al teach methods utilizing at least a carrier matrix, a buffer, a solution of guanidine thiocyanate or a functional equivalent thereof, and an antibody that recognizes PrP^{Sc}. Thus, it would have been obvious at the time the invention was made to one of ordinary skill in the art to prepackage the reagents for such a method into a convenient kit form in order to facilitate the assay of samples.

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5, 10-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997).

The claims are drawn to is a method for reducing the risk of scoring a false-positive test result when testing $\geq$1 sample obtained from a mammal for the presence or absence of an aberrant prion

protein, the method comprising treating said ≥1 sample with guanidine thiocyanate or a functional equivalent thereof, without pre-treating said at least one sample for formic acid; and testing said ≥1 sample for the presence or absence of an aberrant prion protein, wherein said method is an immunoassay designed for mass-screening purposes and further comprising treating said ≥1 sample with a protease to reduce the presence of normal prion protein.

Grathwohl et al teach the claimed method without pre-treating said at least one sample for formic acid (Abstract; page 206, second column, lines 23-27; section 2.2, pages 206-208; Figure 1; section 2.4, page 208; section 3.3, pages 209-212).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 6, 7, 18, and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997).

Claims 6 and 7 are drawn to a method for reducing the risk of scoring a false-positive test result when testing ≥1 sample obtained from a mammal for the presence or absence of an aberrant prion protein, the method comprising treating said ≥1 sample with guanidine thiocyanate or a functional equivalent thereof, without pre-treating said at least one sample for formic acid; and testing said ≥1 sample for the presence or absence of an aberrant prion protein, wherein said method is an immunoassay designed for mass-screening purposes and further comprising treating said ≥1 sample with a protease to reduce the presence of normal prion protein, wherein said mammal is a ruminent and wherein said ruminant is ovine or bovine.

Grathwohl et al teach the claimed method utilizing laboratory mice as sample source without pre-treating said at least one sample for formic acid (Abstract; page 206, second column, lines 23-27; section 2.2, pages 206-208; Figure 1; section 2.4, page 208; section 3.3, pages 209-212).

Grathwohl et al do not teach the claimed method utilizing ruminant, ovine or bovine mammals as the source of the samples, but they do indicate that the method "can also be used to screen sheep and cattle" (page 206, second column, lines 13-14; page 215, column 1, lines 15-45). Thus, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to assay samples from animals which suffer from prion diseases, i.e., ovine, bovine, and ruminants utilizing the methodology of Grathwohl et al.

Grathwohl et al do not teach kits comprising the necessary reagents for performing the immunoassays. However, it would have been obvious at the time the invention was made to one of ordinary skill in the art to prepackage the reagents for such a method into a convenient kit form in order to facilitate the assay of samples.

Conclusion

15. No claims are allowed.

16. Applicant's amendment inserting a new criticality, i.e., no pretreatment of sample with formic acid, necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

April 30, 2005